IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

In re: Valsartan Products Liability Litigation	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Honorable Joel Schneider, Magistrate Judge

MEMORANDUM OF LAW IN SUPPORT OF RULE 12 MOTION TO DISMISS SUBMITTED ON BEHALF OF ALL PHARMACY DEFENDANTS

/s/ Sarah E. Johnston
Sarah E. Johnston
Kara Kapke
Kristen L. Richer
BARNES & THORNBURG LLP
2029 Century Park East
Suite 300
Los Angeles, CA 90067
(310) 284-3798
(310) 284-3894

Counsel for CVS Pharmacy, Inc. (incorrectly named as CVS Health Corporation)

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INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs attribute no misconduct to the Pharmacies they have named as defendants. Instead, Plaintiffs would hold the Pharmacies liable for doing nothing more than properly providing their medically crucial and legally required service: dispensing medication supplied by FDA-approved manufacturers to patients with valid prescriptions from their doctors. With good reason, courts across this country have uniformly rejected that position. This Court should do the same and dismiss Plaintiffs' claims against the Pharmacies.

First, Plaintiffs' claims against the Pharmacies are expressly preempted by the Drug Supply Chain Security Act ("Drug Security Act" or "Act"), 21 U.S.C. §§ 360eee to 360eee-5, Congress' national, uniform framework for tracing prescription drugs throughout the supply chain.

Second, the strict liability and warranty claims and theories asserted would vastly expand the limits of—and proscriptions against—liability for pharmacies dispensing prescription medications, and should be rejected.

Third, Plaintiffs cannot avoid those bars by alleging that the Pharmacies acted negligently, fraudulently, or deceptively in filling patient prescriptions. Plaintiffs have failed to plead a breach of any applicable duty or any other wrongful conduct, and their vague assertion that the Pharmacies "knew or should

have known" of the latent defect in valsartan is a mere conclusory allegation that must be rejected, even at the pleading stage.

Finally, Plaintiffs' claims run afoul of innocent seller statutes enacted in numerous states that explicitly recognize the Pharmacies' unique role in the provision of health care and immunize them from liability in cases like this.

FACTUAL BACKGROUND

The valsartan products at issue are generic versions of the branded medication Diovan, indicated primarily for the treatment of hypertension. Only a licensed healthcare provider may prescribe valsartan, and only a licensed pharmacist may dispense prescribed valsartan to patients.

Although there are more than two dozen FDA-approved manufacturers of generic valsartan,[1] only a handful are at issue in this case. In July 2018, a valsartan manufacturer informed FDA that certain lots of valsartan appeared to contain amounts of a nitrosamine, N-Nitrosodimethylamine ("NDMA")—which otherwise occurs naturally at trace levels in the drug—in excess of the FDA-recommended

[1] FDA's Orange Book, subject to judicial notice, lists the approved manufacturers of generic drugs. *See Otsuka Pharma Co. v. Torrent Pharm. Ltd.*, 118 F. Supp. 3d 646, 655 n.7 (D.N.J. 2015). Attached as Exhibit D is a compendium of the websites cited in this Memorandum, including the valsartan excerpt of the Orange Book, available at https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

daily limit.[2] The sole defect alleged by Plaintiffs—that certain lots of valsartan contained levels of NDMA above this limit—is a latent defect. Plaintiffs plead, as they must, that the defect arose during the manufacturing process and was present at the time of shipment from the manufacturers to the rest of the supply chain. Personal Injury Master Complaint, Dkt. 122 ("PIMC"), at ¶¶ 169, 189-90, 197-98, 232; Economic Loss Master Complaint, Dkt. 398 ("ELMC"), at ¶¶ 246, 336.

Although there are more than 67,000 pharmacies across the United States, and valsartan is a widely prescribed drug, Plaintiffs have sued only the largest pharmacies as defendants ("the Pharmacies"). As key members of the healthcare supply chain, pharmacies are trusted to dispense prescription medications, including valsartan, to customers pursuant to the order of each patient's treating physician. All pharmacies are subject to strict federal and state laws and regulations that outline licensing/registration requirements.[3]

The Pharmacies did not prescribe or recommend valsartan to Plaintiffs, and Plaintiffs do not (and cannot) plead that they did. Nor did the Pharmacies participate in the manufacture of valsartan or engage in any conduct creating the

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[2] *See* PIMC at ¶ 170, citing July 13, 2018 FDA article, available online at https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity.

[3] *E.g.*, Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397; *see also Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-65 (2002).

alleged defect. All the Pharmacies are alleged to have done, and all they could have done, is dispense generic valsartan to patients pursuant to valid prescriptions. *See* PIMC at ¶¶ 92, 96, 99, 107, 113, 115, 117, 119, 121.

Of course, pharmacies are not manufacturers, and they are not physicians. It is the warnings of the manufacturer, not the pharmacist, that are conveyed to a patient when a drug is dispensed. Pharmacies do not market prescription drugs, do not recommend prescription drugs to patients, and do not make promises or extend guarantees regarding the therapeutic benefits of a prescription drug or the sameness of a generic drug to its branded counterpart. Indeed, as Plaintiffs themselves admit, where FDA has approved a generic drug such as valsartan, *"[p]harmacists*, physicians, and patients can expect such generic drugs to be therapeutically interchangeable" with the registered listed drug. ELMC at ¶ 210 (emphasis added).

ARGUMENT

The Manufacturing and Wholesaler Defendants present a number of grounds for dismissal of the Complaints as to all defendants, including lack of standing, implied *Buckman* preemption, and failure to plead the substantive elements of each claim. The Pharmacies adopt these arguments as independent bases for dismissal.[4]

[4] Except for lack of privity, the Manufacturers' arguments apply equally, if not more so, to the Pharmacies. Exhibit A provides a further breakdown of which claims are subject to dismissal because of arguments in other briefs.

Beyond these arguments, the Pharmacies are entitled to dismissal because (I) the Drug Supply Chain Security Act expressly preempts Plaintiffs' claims against them; and (II) pharmacies' unique healthcare role precludes the liability Plaintiffs seek to impose. Plaintiffs' claims against the Pharmacies should be dismissed.[5]

I. PLAINTIFFS' CLAIMS ARE PREEMPTED BY THE DRUG SUPPLY CHAIN SECURITY ACT.

A. The Drug Supply Chain Security Act establishes a framework of requirements governing pharmacies' tracing and investigation of potentially misbranded drugs.

In 2013, Congress passed the Drug Security Act in an effort to secure the supply chain for prescription pharmaceutical drugs. 21 U.S.C. §§ 360eee to 360eee-5. The Act is intentionally broad and comprehensive, governing all trading partners in the supply chain for prescription drugs and establishing a framework of

[5] As against all the pharmacies, whether or not they were named in any of the Master Complaints, this Court should dismiss the three Master Complaints and all individual claims. *See In re: Katrina Canal Breaches Litig.*, 309 F. App'x 836 (5th Cir. 2009). Further, any entities merely mentioned in the Complaints as being affiliated with a Pharmacy Defendant but not named as a defendant should be dismissed. *See Quesinberry v. Messerchmidt*, No. 1:10-00769, 2010 WL 3489377, at *1 (S.D. W. Va. Sept. 1, 2010) (granting motion to quash summons when movant served with summons but not listed as defendant in complaint). In addition, distributors and re-packagers are similarly situated to pharmacies inasmuch as they have no involvement in the manufacturing process at issue; nor do they advertise or make statements about generic drugs to consumers. Although these entities do not share in the pharmacies' unique healthcare role and do not dispense medications to consumers, distributors and re-packagers join in the Pharmacy Defendants' arguments for dismissal, and in particular, adopt Sections II.B.2-II.B.4, as well as any arguments applicable to distributors and re-packagers in the Manufacturing Defendants' and Wholesalers' briefs.

the critical steps necessary to enable the eventual electronic identification and traceability of prescription drugs. For example, since 2015, trading partners have been required to include specific transaction information for most transfers to other trading partners in the supply chain. Since 2018, manufacturers have been required to affix machine-readable product identifiers on drug packages, *see* 21 U.S.C. § 360eee-1(b)(2), and in the future, pharmacies will not be permitted to accept drug packages unless they contain those product identifiers, *see* 21 U.S.C. § 360eee-1(d)(2).

The Act imposes specific obligations on pharmacies, called "dispensers" in the Act's text. First, pharmacies may not accept ownership of a prescription drug unless the previous owner provides specific information about that drug, including its name, its strength and dose, and the manufacturer's confirmation that the drug is what it purports to be and is fit for distribution. 21 U.S.C. § 360eee-1(d)(1)(A)(i), § 360eee(26), (27). The pharmacy must reject a shipment that is missing this information. Second, the Act requires that pharmacies capture various information "as necessary to investigate a suspect product." *Id.* § 360eee-1(d)(1)(A)(iii) (requiring capture of, among other things, transaction history, product name and dose, and a manufacturer's verification of product legitimacy). Suspect products include any drug a pharmacy has reason to believe is adulterated, misbranded, or otherwise unfit for distribution. *Id.* § 360eee(21). Third, pharmacies must

implement a system for quarantining suspect products and determining whether they are unfit for distribution. 21 U.S.C. § 360eee-1(d)(4). Through this web of requirements on pharmacies and others in the supply chain, the Act creates a comprehensive, national framework that sets pharmacies' requirements for identifying, tracing, and isolating adulterated or misbranded drugs.

B. Plaintiffs' claims against the Pharmacies are expressly preempted.

To give effect to the Act, Congress included an express preemption provision that precludes imposition of any state requirement that is "inconsistent with, more stringent than, or in addition to" requirements under the Act, including investigation relating to systems for tracing misbranded or adulterated drugs. 21 U.S.C. § 360eee-4(a).[6] The preemption provision provides uniformity so that trading partners are not subjected to different rules for identifying, tracing and quarantining suspect products.[7] Through this broad preemption clause, the Act sets the rules, and no state requirements can add to or contradict them, including

[6] Congress intended to replace the patchwork of state regulations about what is required when a dispenser accepts a drug from a trading partner. *See* Cong. Rec. H5946, 62, 64 (daily ed. Sept. 28, 2013) (statements of Rep. Latta and Rep. Matheson).

[7] Unlike other express preemption provisions which preempt only those state requirements that are "inconsistent" with federal standards, the Drug Security Act additionally preempts any state requirements for product tracing that are "more stringent than, or in addition to" federal requirements. *Cf. N Meat Ass'n v. Harris*, 565 U.S. 452, 459-60 (2012) (clause that prevents a state from imposing any additional or different requirements "sweeps widely").

via lawsuits. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25 (2008).

Plaintiffs do not plausibly allege that the Pharmacies violated the Drug Security Act. Their claims instead depend on a finding that a pharmacy's *compliance with the Act is not enough* under state common law. But that is precisely what the Act's preemption provision prohibits: state requirements, including common law requirements, that are inconsistent with, more stringent than, or in addition to those imposed by the Act.

Plaintiffs' claims rely on the theory that the Pharmacies have a duty to ensure that a product labeled "valsartan" is, in fact, therapeutically equivalent to valsartan. Were that true, state law would impose duties upon the Pharmacies that are more stringent than the Act's requirements. The Act does not mandate that dispensers identify every misbranded, adulterated, or counterfeit drug—that would be impossible. What it does require is that dispensers capture transaction information and refuse product if a manufacturer does not certify that a product is what it says it is. Plaintiffs' claims threaten the balance Congress struck by imposing requirements on pharmacies beyond the Act's requirements.

For example, Plaintiffs allege that the Pharmacies warranted that the valsartan they dispensed was bioequivalent to valsartan's reference listed drug. ELMC at ¶¶ 437-38 (express warranty), ¶ 461 (implied warranty), ¶ 479

(Magnuson-Moss Warranty Act, based on breach of implied warranty arising under state law). But Plaintiffs allege no trigger requiring the Pharmacies to investigate and verify the "sameness" of these products, and without one, the Act requires no such procedure. Further, the Act requires pharmacies to obtain a specific set of information from suppliers. It does ***not*** require pharmacies to obtain lists of ingredients and impurities, verify information about the manufacturing process, or demand a guarantee that the product is not adulterated. Plaintiffs' pleadings would require pharmacies to insist on obtaining information from their trading partners relating to manufacturing process changes and analyses of chemical syntheses occurring in the interaction of valsartan's raw ingredients, or to perform such chemical tests themselves, all of which would be in addition to and well beyond what the Act requires.

The same analysis confirms preemption of Plaintiffs' other claims. Plaintiffs' fraud, misrepresentation, consumer protection, and product liability claims are also based on the allegation that the valsartan Plaintiffs received was not therapeutically equivalent to valsartan's reference listed drug. ELMC at ¶¶ 493, 520, 548; PIMC at ¶¶ 432-33, 447, 456. Plaintiffs' unjust enrichment claim is dependent on receipt of adulterated and misbranded valsartan. ELMC at ¶ 371, 558. Finally, Plaintiffs claim that the Pharmacies negligently failed "to oversee actions taken in the manufacture and sale of" the dispensed valsartan. *Id.* at ¶ 574.

In effect, all of these claims challenge the Act and FDA's requirements for identifying and investigating potentially adulterated or misbranded product by asserting that compliance with the Act is not enough. The Act sets forth the *maximum* a pharmacy is required to do when accepting product from manufacturers and then tracing it through the supply chain—and it does not require what Plaintiffs propose. Plaintiffs' claims, and the duties and warranties Plaintiffs would impose on pharmacies, would require pharmacies to identify and investigate every single product for "sameness" and safety. This is not what the Act envisions or requires. All of Plaintiffs' claims against the Pharmacies are preempted and should be dismissed.

II. PLAINTIFFS' CLAIMS SHOULD ALTERNATIVELY BE DISMISSED FOR FAILURE TO STATE A CLAIM AGAINST THE PHARMACIES.

Plaintiffs assert two categories of claims against the Pharmacies: (A) those that impose liability without fault (*e.g.,* strict liability, warranty), and (B) those that impose liability for some form of alleged misconduct (*e.g.,* negligence, misrepresentation). Neither category includes a single, viable claim against the Pharmacies.

A. Plaintiffs' strict liability and warranty claims must be dismissed.

First, Plaintiffs seek to impose liability on the Pharmacies even though they acted without fault or knowledge that the dispensed medication contained

nitrosamines. Courts have rejected such claims. Accordingly, Plaintiffs' (1) strict liability claims (Counts 1-3 of PIMC and 4-5 of Plaintiffs' Master Medical Monitoring Complaint, Dkt. 123 ("MMMC")), and (2) express and implied warranty claims (Counts 1, 3, 5 of ELMC, 6-7 of PIMC, and 6-8 of MMMC) should be dismissed. Attached as Exhibit B is a state-by-state summary chart providing citation to authorities warranting the dismissal of these claims.[8]

1. Pharmacies are not subject to liability without fault.

Courts have widely recognized that pharmacies stand apart from the typical "seller" of a product, and are therefore not subject to strict liability for latent defects in drugs they dispense. Cases "have uniformly held" that pharmacies are immune from strict liability. *Ealy v. Richardson-Merrell, Inc.*, No. 83-3504, 1987 WL 159970, at *3 (D.D.C. Jan. 12, 1987). Pharmacies "are not the kind of 'retailers' that strict liability regimes are designed to target." *Herzog v. Arthocare Corp.*, No. Civ. 02-76-P-C, 2003 WL 1785795, at *13 (D. Me. Mar. 21, 2003). Put simply, "[t]he concept of strict liability without fault should not be applied to

[8] All authorities cited in Exhibits B and C are hereby expressly incorporated by reference into the Pharmacy Defendants' motion to dismiss and this memorandum of law in support thereof. For the Court's convenience, all non-reported and unpublished cases cited in this brief are compiled in two compendiums submitted herewith: (1) Compendium of Unpublished Judicial Opinions Referenced in the Pharmacy Defendants' Memorandum of Law, attached as Exhibit E; and (2) Compendium of Unpublished Judicial Opinions Referenced in Exhibits B and C to the Pharmacy Defendants' Memorandum of Law, attached as Exhibit F.

the prescription druggists in the instant situation." *McLeod v. W.S. Merrell Co.*, 174 So.2d 736, 739 (Fla. 1965); *see also In re: N.Y. Cnty. Diet Drug Litig.*, 691 N.Y.S.2d 501 (App. Div. 1st Div. 1999) (rejecting pharmacy strict liability). There are many reasons for this immunity.

First, courts have appropriately recognized that pharmacies perform a service of dispensing a product prescribed by a physician, and that imposing liability on pharmacies without fault would interfere with the delivery of healthcare services to patients and undercut the important role pharmacies play as adjuncts to the physician-patient relationship. *Madison v. Am. Home Prod. Corp.*, 595 S.E.2d 493, 495 (S.C. 2004) (rejecting strict liability). Physicians write prescriptions and pharmacists generally do not "substitute [their] judgment of the product's safety for the patient for that of the physician." *Coyle by Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1387 (Pa. 1991). As explained by the California Supreme Court, "[i]f pharmacies were held strictly liable for the drugs they dispense, some of them, to avoid liability, might restrict availability by refusing to dispense drugs which pose even a potentially remote risk of harm, although such medications may be essential to the health or even the survival of patients." *Murphy v. E.R. Squibb & Sons*, 40 Cal. 3d 672, 680-681 (Cal. 1985) (noting the same for less expensive generic drugs).

Second, the policy objectives of strict liability are inapplicable to pharmacies, as they are not in a position to ensure the safety of a drug or how it is manufactured because of the unique nature of their physician-directed services. "One of the purposes of imposing strict liability or liability for breach of warranty on retailers is to encourage retailers to pressure manufacturers to make safer products. Yet this goal is lost on pharmacists, who have little or no impact on a manufacturer's marketing of prescription drugs." *In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 292 (S.D.N.Y. 2001); *see also Abrams v. Bute*, 138 A.D.3d 179, 186 (N.Y. App. 2d Div. 2016) ("The responsibility of providing information about the potential hazards of a prescription drug properly falls most heavily on the manufacturer who stands in the best position to recognize and cure defects.") (internal quotation marks omitted). At bottom, "[i]t would be senseless, especially given drug regulation by the Food and Drug Administration and the extensive tort liability of drug manufacturers, to make pharmacies liable in tort for the consequences of failing to investigate the safety of thousands of drugs." *Walton v. Bayer Corp.*, 643 F.3d 994, 1000 (7th Cir. 2001) (affirming dismissal of fraudulently joined pharmacy). Absent proof of negligence or fault, a pharmacy's liability is "merely derivative" of the manufacturer's, and claims against the pharmacy must be dismissed. *Lansdell v. Am. Home Prod. Corp.*, No. Civ.A. CV99S2110NE, 1999 WL 33548541, at *6–7 (N.D. Ala. Oct. 26, 1999) (finding

pharmacy fraudulently joined); *see also Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 932 (Utah 2003) ("Whether their pharmaceutical practice is improper or excessive is a question of negligence, not strict liability, so long as the conduct occurs within the standard framework of pharmacists."); *McKenna v. Harrison Mem'l Hosp.*, 960 P.2d 486 (Wash. Ct. App. 1998) (dismissing claim against hospital that provided defective medical device, noting that pharmacists are exempt from strict liability).

To the extent Plaintiffs plead that the Pharmacies did not dispense valsartan, but instead an adulterated and misbranded drug, that theory of liability fails for the reasons set forth in the Manufacturers' brief at 19-23, Part III. However, whatever force such arguments have against the Manufacturers, there is simply no basis for liability as to the Pharmacies. Case law is clear that it is the manufacturer's responsibility, not the pharmacy's, to warn of any latent defect.

> To hold a druggist strictly liable would be to make the druggist an insurer of the safety of the manufactured drug and would impose on the retail druggist the obligation to test, at its own expense, new drugs. The costs to society, which needs and values the pharmaceutical products sold by druggists, would be unduly high. Therefore, a druggist should not be an absolute insurer.

Ramirez v. Richardson-Merrell, Inc., 628 F. Supp. 85, 87 (E.D. Pa. 1986); *see also McLeod*, 174 So. 2d 736 (rejecting application of strict liability because it would "convert the retail prescription druggists into insurers of the safety of the manufactured drug").

Plaintiffs' strict liability claims against the Pharmacies wholly ignore courts' widespread rejection of such claims and should be dismissed.

2. Plaintiffs fail to plead warranty claims against the Pharmacies.

Plaintiffs' claims for breach of implied and express warranty fare no better. Rooted in contract law, warranty claims seek to impose liability where "the goods purchased are below commercial standards or are unfit for the buyer's purpose." *Altronics of Bethlehem, Inc. v. Repco, Inc.*, 957 F.2d 1102, 1105 (3d Cir. 1992). Like strict products liability, warranty liability typically attaches without regard to fault. *See* ELMC at ¶ 409 (referencing "strict liability implied warranties"). Thus, for the same reasons that courts have rejected strict products liability claims against pharmacies, they also reject claims that a pharmacy breached an express or implied warranty by dispensing a prescription drug with a latent defect. Because there is a "clear national consensus" on this point, *Salisbury v. Purdue Pharma, L.P.*, 166 F. Supp. 2d 546, 551 (E.D. Ky. 2001), Plaintiffs' warranty claims against the Pharmacies should be dismissed.

a) A pharmacy dispensing prescription drugs does not furnish an implied warranty to the patient.

Implied warranty claims are based on a seller's status as a merchant of goods. But pharmacies provide a *service* by filling a doctor's orders. They are not considered "merchants" or "sellers," but rather serve "as an extension of the doctor

in the same sense as a technician who takes an X-ray or analyzes a blood sample on a doctor's order." *Murphy*, 40 Cal. 3d at 679. A pharmacy does not "sell" a "good" subject to implied warranties under the UCC because the pharmacist is merely a "necessary step in completing the treatment regimen selected by the patient's physician." *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 692 F. Supp. 2d 1025, 1036-37 (S.D. Ill. 2010) (finding that pharmacists predominantly provide "professional healthcare services," and thus "Plaintiff's breach of warranty claim has no reasonable chance of success"), *aff'd sub nom. Walton v. Bayer Corp.*, 643 F.3d 994 (7th Cir. 2011); *see also Carrozza v. CVS Pharm., Inc.*, 391 F. Supp. 3d 136, 148 (D. Mass. 2019) ("It is undisputable that [the pharmacy's] dispensing of Levaquin was primarily a 'rendition of service' immune from the UCC's liability scheme."), *appeal filed*, No. 19-1776 (1st Cir. Aug. 7, 2019). Put simply, "implied warranties do not apply to the dispensing of medication by a pharmacist." *Presto v. Sandoz Pharm. Corp.*, 487 S.E.2d 70, 75 (Ga. Ct. App. 1997).

Implied warranty claims against pharmacies also fail because patients do not bargain with pharmacists about the suitability of the drug dispensed. *See, e.g.*, *In re Rezulin*, 133 F. Supp. 2d at 291. "The only representations regarding the intrinsic properties of the drug that form the basis of the buyer's purchase are those of the physician." *Id.*

Numerous courts have found the basis for imposing warranty or other liability on pharmacies to be so tenuous that plaintiffs cannot even meet the fraudulent joinder standard[9] regardless of the theory of liability, and pharmacies have been dismissed in such instances. *See, e.g.*, *Duckett v. SCP 2006-C23-202, LLC*, 225 F. Supp. 3d 432, 436 (D.S.C. 2015); *Smith v. Wyeth, Inc.*, 488 F. Supp. 2d 625 (W.D. Ky. 2007); cases cited in Exhibit B.

To avoid dismissal of their claims, Plaintiffs conjure an alleged violation of an express or implied warranty of "sameness." *See* ELMC at ¶ 493. They plead that the Pharmacies warranted to each patient that the generic drug dispensed to them was "the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics." *Id.* at ¶ 408. This theory fails for the reasons set forth in the Manufacturers' Brief at 24-26, Part III. Moreover, in the context of pharmacies dispensing generic drugs, the obligation to confirm that an FDA-approved generic medication is bioequivalent to its branded counterpart falls squarely on the

[9] Cases involving the claimed fraudulent joinder of pharmacy defendants are telling, because the fraudulent joinder standard in many courts is more permissive than that applied to a Rule 12(b)(6) motion. *See, e.g.*, *Batoff v. State Farm Ins. Co.*, 977 F.2d 848, 851-54 (3d Cir. 1992) (the inquiry under Rule 12(b)(6) is "more searching than that permissible when a party makes a claim of fraudulent joinder"); *see also Ceballo v. Mac Tools, Inc.*, No. 11-4634, 2011 WL 4736356 (D.N.J. Oct. 5, 2011). A theory of liability that cannot survive fraudulent joinder review cannot survive a Rule 12(b)(6) motion.

manufacturer, not the pharmacy. *See* ELMC ¶ 210 (pharmacies can expect FDA-approved drugs from manufacturers to be bioequivalent to the registered listed drug). At most, pharmacies warrant that they are properly dispensing the drug prescribed as the pharmacy received it from an FDA-approved manufacturer.[10]

The law, with abundant uniformity, does not recognize this type of liability against pharmacies, and Plaintiffs' warranty claims should be dismissed.

b) Plaintiffs have not identified any express warranty at all, let alone pleaded a breach of one.

Plaintiffs' breach of express warranty claim fails for the reasons set forth above and also suffers from another fundamental (and fatal) deficiency: Plaintiffs fail to identify a specific promise or representation made by a Pharmacy that formed the basis of a plaintiff's decision to purchase valsartan. *See, e.g.*, *Mladenov v. Wegmans Food Markets, Inc.*, 124 F. Supp. 3d 360, 378 (D.N.J. 2015) (plaintiff must state the warranty, plead they "saw" it and "purchased [the product] as a result"); *Walters v. Carson*, No. 11-6545, 2012 WL 6595732, at *3 (D.N.J. Dec. 17, 2012); Manuf. Br. at 47-49, Part V.E.3.

[10] Hypothetically, the analysis might be different if, for example, a pharmacy told a patient it had dispensed one drug but in fact had dispensed a wholly different medication. Plaintiffs have not pleaded such a case here, and any determination whether nitrosamine-containing valsartan constitutes a "new" or "different" drug under the complex federal regulations governing approved generic drugs lies squarely and solely within the jurisdiction of FDA. *See* Manuf. Br. at 19-26, Part III.

That Plaintiffs failed to meet this pleading requirement is unsurprising. The Pharmacies did not urge Plaintiffs to take valsartan, made no representation that induced Plaintiffs to fill their valsartan prescriptions, and did not market valsartan to Plaintiffs as superior to other available antihypertensive medications. No Plaintiff has suggested that they were convinced to take generic valsartan manufactured by a specific defendant over branded Diovan or valsartan manufactured by one of the many FDA-approved manufacturers not implicated in this litigation. Indeed, many states and insurance plans require pharmacies to fill prescriptions with available, approved generics unless expressly directed otherwise. *See* Guy V. Amoresano, *Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground*, 62 Food & Drug L.J. 249, 250 (2007).

There was no express warranty given by the Pharmacies, and no bargaining between patient and pharmacist at all. Plaintiffs filled their physicians' prescriptions for valsartan, and the Pharmacies, as they must, followed the physicians' orders. In the absence of any express warranty, Plaintiffs' express warranty claims should be dismissed. *E.g.*, *In re Rezulin*, 133 F. Supp. 2d at 291.

B. Plaintiffs have not alleged a basis to hold the Pharmacies liable for negligence or other actionable misconduct.

As with their no-fault causes of action, Plaintiffs' fault-based claims against the Pharmacies likewise fail. Plaintiffs have not and cannot plead that the Pharmacies breached an applicable standard of care, and their fraud,

misrepresentation, unjust enrichment, and consumer protection claims fail to meet the pleading standards of Rule 8 and Rule 9(b).

1. Plaintiffs have failed to plead breach of an appropriate standard of care in their negligence claims.

Pharmacies do not have a duty to test or inspect dispensed drugs, and Plaintiffs cannot plausibly state a claim that the Pharmacies should have known of the alleged valsartan impurity. The existence of a legal duty, and its breach, are prerequisites to a negligence claim. *See, e.g.*, *Smith v. Sci. Games Corp.*, 461 F. App'x 151, 153 (3d Cir. 2012) ("Whether there is a duty of care is a matter of law for the court to decide.") (citing *Carvalho v. Toll Bros. & Developers*, 675 A.2d 209, 212 (N.J. 1996)). Because Pharmacies have no duty to test the drugs they dispense, there was not, and could not have been, a breach of any such duty, and the Pharmacies are entitled to dismissal of Plaintiffs' negligence-based claims in Counts 4-5 of the PIMC, 15 and 17 of the ELMC, and 1-3 of the MMMC.

Pharmacies do not have a duty to test prescription drugs, as Plaintiffs assert in their "general" allegations applicable to all Defendants. *See* PIMC at ¶¶ 417, 420, 426. *See Winters v. Alza Corp.*, 690 F. Supp. 2d 350, 354 (S.D.N.Y. 2010) ("[A] pharmacist does not have a duty to inspect or test a prescription drug for latent dangers.") (citing *Bichler v. Willing*, 397 N.Y.S.2d 57 (N.Y. App. Div. 1977)). As found by the Sixth Circuit in affirming judgment for a pharmacy, "[Plaintiff] further claims that [the pharmacy defendant] had the duty to investigate

and test any prescription medications it sold before dispensing them to customers, but there is no law to support this assertion." *Flint v. Target Corp.*, 362 F. App'x 446, 448–49 (6th Cir. 2010). Plaintiffs cannot point to any law—because there is none—suggesting that pharmacies have a duty to test prescription drugs.[11]

Further, Plaintiffs plead a *latent* defect, identifiable only after extensive testing, including a unique analytical method FDA developed and approved in 2018.[12] Although Plaintiffs allege that the Pharmacies were negligent in failing to detect this latent defect prior to dispensing valsartan to patients, an overwhelming weight of authority holds that a vendor has no "duty to inspect or test a product manufactured by another for latent defects either before or after it has been sold to a third party." *Champion Mobile Homes v. Rasmussen*, 553 S.W.2d 237, 243 (Tex. Civ. App. 1977); *see also, e.g.*, *Noveck v. PV Holdings Corp.*, 742 F. Supp. 2d 284,

[11] This rule is consistent with FDA's rejection of non-manufacturer testers. In response to a Citizens' Petition, FDA confirmed that manufacturers of a drug are "most familiar with their own processes, facilities and supply chains, and are therefore best placed to assess a risk." Decision from FDA CDER to Valisure, LLC, No. FDA-2019-P-4281-0008 at 12-13 (Apr. 1, 2020), https://www.regulations.gov/document?D=FDA-2019-P-4281-0008.

[12] "Because it was not anticipated that NDMA would occur at these levels," FDA scientists observed, even "manufacturers would not have been testing for it." Scott Gottlieb and Janet Woodcock, FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings (Aug. 30, 2018), https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-impurities-and-recalls-and-update-fdas-current.

299 (E.D.N.Y. 2010) ("[W]hen a defect is discoverable only by special tests or by an expert's examination, a retailer will generally not be liable for failure to discover") (quoting *Topliff v. Wal-Mart Stores East LP*, No. 6:04-CV-0297, 2007 WL 911891, at *4 (N.D.N.Y. Mar. 22, 2007)). Plaintiffs' assertions even contradict their own admission that the Pharmacies, like Plaintiffs themselves, can rely on FDA's approval and the manufacturers' affirmations of sameness. ELMC at ¶ 210 ("Pharmacists, physicians, and patients can expect [FDA-approved] generic drugs to be therapeutically interchangeable[.]").

The Pharmacies cannot be held liable for failing to detect the presence of nitrosamine in the valsartan they dispensed, and Plaintiffs' negligence claims based on an alleged duty to do so should be dismissed.

2. Plaintiffs fail to adequately plead actual or constructive knowledge triggering a duty to act.

Plaintiffs' conclusory allegation that the Pharmacies "should have known" of the nitrosamine impurity are insufficient to save their negligence claims. First, this allegation is directly contradicted by Plaintiffs' contention that the manufacturers concealed the presence of nitrosamine in valsartan. The Pharmacies did not know and could not have known the manufacturing defendants were, as Plaintiffs allege, "conceal[ing] and destroy[ing] evidence . . . to willfully and recklessly introduce adulterated and/or misbranded VCDs into the U.S. market." PIMC at ¶ 198; *see also* ELMC at ¶ 241; MMMC at ¶ 308.

Second, setting aside this contradiction in the pleadings, vague assertions as to what parties "should have known," without additional facts demonstrating the Pharmacies' knowledge of the presence of nitrosamine in valsartan, fail to satisfy fundamental pleading requirements. Formulaic recitations of the elements of a claim "will not do." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see also Butera v. Honeywell Int'l*, No. 18-13417, 2020 WL 64568, at *7 (D.N.J. Jan. 6, 2020) (pleadings failed to "allege any facts to support a finding that membership in the industry gave Defendant actual or constructive knowledge" of defect); *Giles v. Wal-mart Louisiana LLC*, No. 16-2413, 2016 WL 2825778, at *6 (E.D. La. May 13, 2016) ("Plaintiff's bald assertion that all Defendants had actual or constructive knowledge of the allegedly defective condition is a conclusory allegation that the Court is not required to accept.").

Even under the more permissive fraudulent joinder standard, courts have routinely rejected conclusory allegations regarding actual or constructive knowledge in cases involving pharmacists dispensing prescription drugs where, as here, the complaint simultaneously alleges concealment of the information by the manufacturing co-defendants. This is because the "impossibility of the claim" against the pharmacy "is implicit in the contradictory allegations. . . . In each of these cases, the premise of the case against the non-diverse defendant(s) that they knew or should have known of the dangers is *undercut, defeated, and made*

impossible by the claims of fraud and misrepresentation against the manufacturers." *Baisden v. Bayer Corp.*, 275 F. Supp. 2d 759, 762-63 (S.D. W. Va. 2003) (citing numerous cases and finding non-diverse defendant fraudulently joined) (emphasis added).

Other courts likewise have rejected "bald allegations" of negligence against pharmacies in the fraudulent joinder context. *See In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 624 F. Supp. 2d 396, 424 (E.D. Pa. 2009) (failure "to use reasonable care" in selling prescription drug was too conclusory to state a claim) (quoting *Locicero v. Sanofi Aventis U.S., Inc., et al.*, No. 07-CV-00618, 2007 WL 717880, at *3 (W.D.N.Y. Nov. 7, 2007); *see also In re Diet Drugs*, No. MDL 1203, Civ.A. 03-20284, 2004 WL 1925010, at *1 (E.D. Pa. Aug. 30, 2004) (dismissing pharmacy under Louisiana law because complaint fell "far short" of alleging pharmacy knew or should have known the dangers of prescription).

Without plausible, factual underpinnings supporting the allegation that the Pharmacies should have known of the nitrosamine impurity, Plaintiffs' negligence claims against the Pharmacies based on this theory should be dismissed.

3. Plaintiffs inadequately plead fraud and misrepresentation.

Plaintiffs' claims that the Pharmacies fraudulently dispensed valsartan or misrepresented its quality also fail to satisfy federal pleading requirements under Rule 8 and Rule 9(b). *See* Manuf. Br. at 35-38, Part V.A. As discussed

immediately above, Plaintiffs failed to plead facts sufficient to demonstrate that the Pharmacies had actual or constructive knowledge of the nitrosamine impurity. Vague and conclusory statements regarding all Defendants, without differentiation as to each party's conduct, fail to satisfy Rule 9's requirement that for claims sounding in fraud, the plaintiff must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see Snyder v. Dietz & Watson, Inc.*, 837 F. Supp. 2d 428, 450 (D.N.J. 2011); *Mayor and Council of Rockaway v. Klockner & Klockner*, 811 F. Supp. 1039, 1060 (D.N.J. 1993).

Moreover, Plaintiffs fail to plead a viable basis for the misrepresentation element of their claims. As discussed above, any claims seeking to impose liability because the Pharmacies misrepresented that the valsartan complied with FDA requirements, or was bioequivalent to the branded equivalent or reference listed drug, is not only preempted by federal law, but is also a duty that falls squarely on valsartan's manufacturers, not pharmacies dispensing this medication. *See* ELMC at ¶ 210 (admitting that manufacturers, not pharmacies, make warranties of bioequivalence).

Because Plaintiffs have failed to plead actionable fraud or misrepresentation, Counts 8 and 9 of the PIMC, 7 and 9 of the ELMC, and 9 of the MMMC against the Pharmacies are deficient and should be dismissed.

4. Plaintiffs' remaining claims fail as a matter of law.

Plaintiffs' unjust enrichment and consumer protection claims fail for the reasons set forth above and as presented in the Manufacturers' Brief at 27, Part III; 50-53, Part V.F. Additionally, as to unjust enrichment, Plaintiffs' singular claim against the Pharmacies (Count 13 of the ELMC) fails[13] because Plaintiffs' multiple warranty claims based on the alleged contract formed between Plaintiffs and the Pharmacies at the time of sale provide adequate remedies at law. *See, e.g.*, ELMC at ¶ 437 (alleging contract). The law is unanimous in all eighteen states for which there is a named class representative in the ELMC that unjust enrichment claims fail in such circumstances. *See* Exhibit C (state-by-state summary chart providing citation to authorities warranting the dismissal of such claims). Plaintiffs' unjust enrichment claim must be dismissed even though their warranty claims also fail, because "[i]t is the availability of a remedy at law, *not the viability of that remedy*, that prohibits a claim for unjust enrichment." *E.g.*, *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 16 (1st Cir. 2017) (applying Massachusetts law and dismissing plaintiff's unjust enrichment claim even though plaintiff's other legal claims were dismissed) (emphasis added).

Plaintiffs' requested remedy of disgorgement of profits should also be dismissed because it is tied only to their unjust enrichment claim, which fails, as

[13] Neither the PIMC nor the MMMC alleges a claim for unjust enrichment.

noted above. In addition, the extraordinary remedy of disgorgement is only appropriate where a tortfeasor's conscious wrongdoing requires it. *See* Restatement (Third) of Restitution and Unjust Enrichment § 3 cmt. a (Am. Law. Inst. 2011) ("Liability to disgorge profits is ordinarily limited to cases of . . . 'conscious wrongdoing,' because the disincentives that are the object of a disgorgement remedy are not required in dealing . . . with inadvertent tortfeasors."); *accord In re Cheerios Mktg. & Sales Practices Litig.*, No. 09-cv-2413, 2012 WL 3952069, at *13 (D.N.J. Sept. 10, 2012). A '"conscious wrongdoer' is a defendant who is enriched *by misconduct* and who acts (a) *with knowledge* of the underlying wrong to the claimant, or (b) despite a *known* risk that the conduct in question violates the rights of the claimant." Restatement (Third) of Restitution and Unjust Enrichment § 51.3 (emphasis added). *See, e.g.*, *Cnty. of Essex v. First Union Nat'l Bank*, 891 A.2d 600, 605-06 (N.J. 2006) (disgorgement appropriate for bribing public official); *S.E.C. v. Hughes Capital Corp.*, 917 F. Supp. 1080, 1085 (D.N.J. 1996) (disgorgement appropriate for securities fraud), *aff'd*, 124 F.3d 449 (3d Cir. 1997); *see also* Wholesalers' Br. at 14-17 (Part III.A, Part III.B).

Here, Plaintiffs have not pleaded any conscious wrongdoing that warrants disgorgement of the Pharmacies' profits to Plaintiffs. Plaintiffs have not alleged that the Pharmacies acted in bad faith, that the Pharmacies diverted profits that

otherwise would have gone to Plaintiffs, or any "misconduct" that would warrant such an extraordinary remedy. Rather, the Pharmacies dispensed valsartan manufactured by the Manufacturers and prescribed by Plaintiffs' physicians that, *unbeknownst to the Pharmacies*, may have contained an impurity. The Pharmacies are the opposite of "conscious wrongdoers," and disgorgement is inappropriate. *See In re Cheerios*, 2012 WL 3952069, at *13 (holding that disgorgement is not available (1) from "innocent recipients" or "inadvertent tortfeasors," (2) when "a consumer purchases specific goods and receives those same specific goods," or (3) when unjust enrichment is not viable); *Airhawk Int'l, LLC v. Ontel Prods. Corp.*, No. 18-cv-00073, 2020 WL 2306440 (S.D. Cal. May 8, 2020) (summary judgment to defendant on disgorgement claim was appropriate where plaintiff failed to show that defendant acted with a culpable mental state sufficient to demonstrate that disgorgement of profits was an appropriate remedy). Any claim for disgorgement should be dismissed.

Similarly, as to Plaintiffs' consumer protection claims (Count 10 of the PIMC and Count 11 of the ELMC), Plaintiffs have not averred on any sustainable basis that the Pharmacies engaged in any deceptive or unjust acts. Rather, Plaintiffs seek to impose liability on the Pharmacies for failure to warn about an alleged latent defect that the Pharmacies did not know and could not have known about. *See* PIMC at ¶ 521-22, ¶ 575-576; *see also In re Yasmin*, 692 F. Supp. 2d at

1038 (rejecting consumer fraud statutory claim against pharmacy). Whether premised upon strict liability or fault-based, Plaintiffs' consumer protection claims against the Pharmacies represent a dramatic and unprecedented form of liability that, research suggests, has never before been permitted. To allow these claims to go forward would "require[] every pharmacist to act as a sort of shadow FDA, making decisions about what types of drugs are and are not safe for the public as a general matter. There is simply no reason to believe that pharmacists are—or should be—equipped to make those sorts of decisions, and asking them to do so would entail a dramatic expansion of their duties[.]" *Winters v. Alza Corp.*, 690 F. Supp. 2d at 356 (granting pharmacy's motion for judgment on the pleadings).

III. STATE "INNOCENT SELLER" LAWS ALSO PROTECT THE PHARMACIES FROM LIABILITY.

As discussed above, courts have given pharmacies protections beyond those given to typical sellers because of pharmacists' role in providing a vital healthcare service. And to the extent Plaintiffs seek to hold the Pharmacies liable as "sellers," Plaintiffs' claims in certain states also are foreclosed by statutory protections for non-manufacturing sellers, as outlined more specifically in the state-by-state summary at Exhibit B and the Wholesalers' Brief at 5-7 (Part I.A).

By Plaintiffs' own allegations, the Pharmacies meet the requirements for dismissal under these innocent seller statutes. First, the product manufacturers are identified and already parties to this litigation. Second, as required by some of

these statutes, the Pharmacies did not modify, alter, or exert control over the design, labeling, or manufacture of the product. Plaintiffs' own allegations make this abundantly clear. *See, e.g.,* PIMC at ¶¶ 236, 247.

Third, as required by some of these statutes, the Pharmacies did not have actual or constructive knowledge of the defect at issue. As discussed above, Plaintiffs have not plausibly alleged that the Pharmacies had actual knowledge of valsartan's nitrosamine impurity before its recalls, nor do they allege that the Pharmacies dispensed any recalled product after the recalls. *See also infra* Part II.B.2 (discussing failure to plausibly plead constructive knowledge). Because the Pharmacies are entitled to the protections of innocent seller laws, they are entitled to dismissal of Plaintiffs' claims as outlined above and supported in the Exhibits.

CONCLUSION

For the foregoing reasons, as well as those reasons applicable to the Pharmacies as outlined in the co-defendants' briefs, the Pharmacies respectfully request the dismissal of all claims against them.

Dated: July 17, 2020

Respectfully submitted,

/s/ Sarah E. Johnston

Sarah E. Johnston
Kara Kapke
Kristen L. Richer
BARNES & THORNBURG LLP
2029 Century Park East
Suite 300
Los Angeles, CA 90067

(310) 284-3798
(310) 284-3894

Counsel for CVS Pharmacy, Inc.
(incorrectly named as CVS Health Corporation)

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of July, 2020, I caused the foregoing Memorandum of Law in Support of Rule 12 Motion to Dismiss Submitted on Behalf of all Pharmacy Defendants to be filed electronically through the CM/ECF system, which will send notice of filing to all CM/ECF participants.

/s/ Sarah E. Johnston
Sarah Johnston